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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/659,490
Filing Date: September 10, 2003
Appellant(s): DEVRIES ET AL.

Glenn M Seager
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/06/2010 appealing from the Office action mailed 11/30/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-10 and 65-69.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,425,855	Tomonto	7-2002
2004/0024444 A1	Moore	2-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 67** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 first recites wherein the first end of the medical device and first composite elongated member are "in a first direction from the second end of the" medical device or first composite elongated member, respectively. However, it is unclear what is meant by "in a first direction." Does that infer they are on opposite sides of the device? Claim 66 also recites wherein "the axis of the first composite elongated

member at the first end ... is offset from the axis of the composite medical device." However, it is unclear as to which axis is referred to.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-4, 6-10, and 65-69** are rejected under 35 U.S.C. 102(b) as being anticipated by Tomonto (US 6,425,855 B2).

With regard to **claims 1-4, 10, and 65**, Tomonto discloses a composite medical device (see entire document) having at least one elongate member, each strut (Figure 1). Each elongated member comprises an inner superelastic material (80) and an outer plastically deformable material (20, 30, or 40) (Figure 2; column 4, lines 20-50). Tomonto teaches the outer plastically deformable layer as sandwiching the inner superelastic material, which clearly overlaps the instantly claimed encasing (column 4, lines 52-56). Additionally, as shown in Figure 1, the outer layer is external to and directly attached to the inner layer on multiple sides so that the outer layer clearly surrounds the inner layer. The superelastic material is further disclosed as Nitinol, a shape memory alloy, and the plastically deformable material as stainless steel or titanium (column 4, lines 44-50). Therefore, the inner material is more elastic than the outer material. As shown in Figure 2, the medical device comprises at least one region

of an exposed inner material where a portion of the outer material (20, 30, or 40) is vacant (column 5, lines 45-51). Therefore this region would inherently have increased flexibility.

The composite medical device of Tomonto is a stent, which moves from a collapsed position to an expanded position at the target site. Since the inner layer of the stent comprises Nitinol, the inner layer biases the medical device to the expanded position (column 1, lines 43-60).

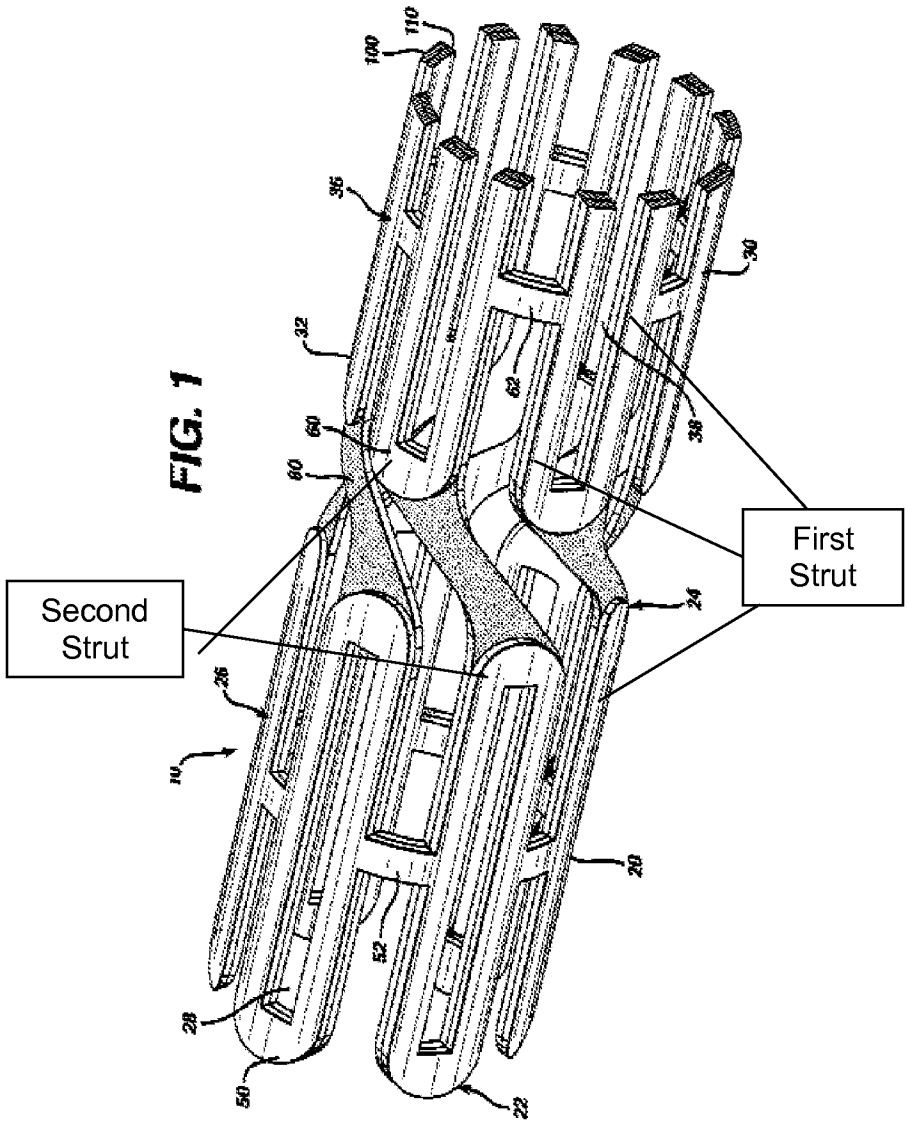
Additionally, as shown in Figures 1 and 3, the elongate members of the stent each comprise a solid cross-section along their entire length. Each strut is solid since it comprises the inner and outer layer without a gap between

With regard to **claims 6-8**, the limitations presented are product-by-process and therefore given no patentable weight. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Once a device in the prior art has been found which is the same or substantially similar, it is encumbered upon applicant to show a non-obvious difference.

With regard to **claim 9**, it is the examiner's position that the stent of Tomonto overlaps the instantly claimed intravascular filter. When placed in a bifurcated vessel at

the produced fork, the stent can act as a filter. Furthermore, merely calling the device a "filter" does not impart a structure to be patentably distinguished over the prior art.

With regard to claim 66, as shown below, Tomonto discloses more than one strut so that a first strut overlaps the claimed first composite elongated member and a second strut overlaps the claimed second composite elongated member. Every strut comprises the disclosed inner and outer layers.



With regard to **claims 67 and 68**, as shown in Figure 2, the medical device and first composite elongated member both comprise central longitudinal axes. Additionally, the first ends of the device and first composite elongated member are both on opposite sides from second ends of the device and first elongated member. Lastly the longitudinal axis through the center of the medical device is offset from the longitudinal axis running through the first composite elongated member since the first composite member is located at the edge of the device. Therefore, the angle between these two axes is non-zero.

With regard to **claim 69**, both composite elongated members extend from the proximal end to the distal of the device so both extend in at least one direction the same, the claimed first direction (Figure 2).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonto (US 6,425,855 B2) in view of Moore (US 2004/0024444 A1).

Tomonto discloses a composite medical device comprising a stent having an inner superelastic material and an outer plastically deformable material. However, Tomonto does not specifically disclose the outer layer of the stent as coated with a polymeric layer.

Moore discloses a stent that preferably coated with a polymeric layer in order to minimize adverse interaction with the walls of the blood vessel or blood flowing through the vessel ([0064]). Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the stent of Tomonto to comprise an outer polymeric coating for the advantages disclosed by Moore.

(10) Response to Argument

Specifically, Appellant argues (A) Tomonto does not disclose an "outer member surrounding and encasing the inner member" since Tomonto discloses outer layer 100 that contacts inner layer 110 only along one side, as shown in Figure 3 of Tomonto.

With respect to argument (A), although Tomonto teaches one embodiment wherein outer layer 100 is formed only along one side of inner layer 110, Tomonto also teaches an embodiment wherein the stent comprises more than two layers. Specifically, this embodiment comprises an inner Nitinol layer "sandwiched" between two layers of stainless steel (column 4, lines 50-56). Therefore, the inner Nitinol

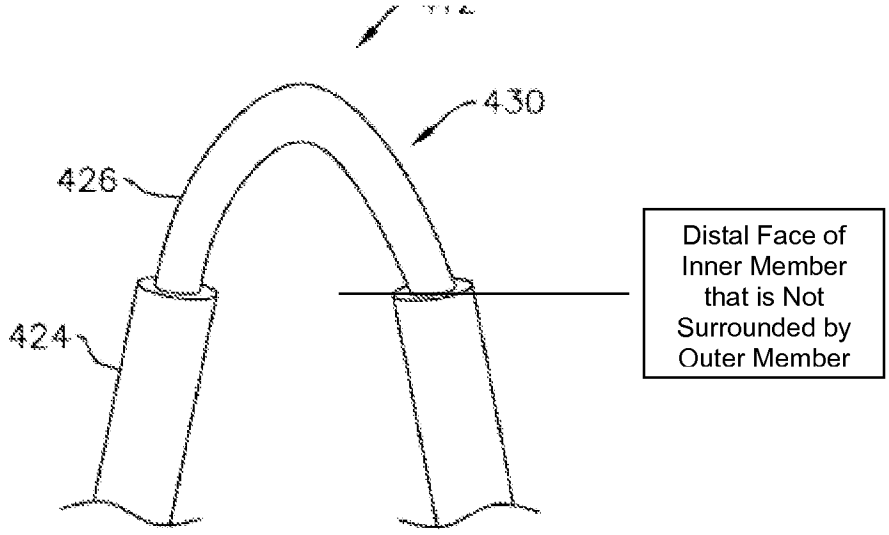
member is surrounded by the outer stainless steel member along at least two sides. The final office action specifically discuses this embodiment to meet the claim limitations (see page 3 of the final office action).

Page 3 of the final office action specifically recites wherein each strut, and not the entire stent device, overlaps the claimed elongate member (page 5 specifically shows at least two struts). Therefore, each elongate member, strut, of Tomonto comprises at least three layers of solid material, an inner Nitinol layer surrounded on at least two sides by an outer stainless steel layer.

Appellant further argues that to surround and encase, the outer member must completely surrounded the inner member. First it is not clear if Appellant is arguing complete enclosure before or after the flexibility regions are formed on the elongated member. If complete enclosure is required by the claims before the flexibility regions are formed then the claim is merely limited to a device wherein the outer layer completely surrounds the inner but specific portions of the outer layer are then subsequently removed to expose the inner member. This removal is a product by process limitation so Tomonto meets the final product and therefore overlaps the claims.

If complete enclosure is required after the flexibility regions are formed, Appellant does not even show such limitations. Appellant argues to surround requires the outer member to "enclose on all sides" (page 10 of the appeal brief). However, as shown below, the instant Figure 17 shows a distal face of the inner member that is not

enclosed by the outer member. Although the outer member surrounds the inner member along its length, it does not surround the very distal and proximal sides.



Additionally, the instant claims do not recite wherein the outer member completely surrounds and completely encases the inner member. Applicant argues that to surround requires "to enclose on all sides" and wherein enclose is defined by "to fence off" (pages 10 and 11 of the appeal brief). If one were to enclose a piece of land with a fence, this fence would surround the land but not completely surround it. A fence comprises holes and breaks formed by the posts. Therefore, it is the Examiner's position that there is distinction between to surround and to completely surround.

Tomonto teaches a stent wherein each struts comprises three layers of material so that an outer member "sandwiches" the inner member. Therefore, the outer member surrounds and encases the inner member, just as two slices of bread surround and encase a slice of turkey. The outer members "hold in" in the inner member so that they

surround and enclose the inner member (see Appellant's definition of enclose on page 11 of the appeal brief).

Specifically, Appellant argues (B) Tomonto is silent with respect to the relative elasticity of the Nitinol (second material) and stainless steel (first material) so that one cannot conclude that the second material is more elastic than the first material.

With respect to argument (B), Appellant first concedes that some Nitinols are more elastic than some stainless steels (page 13 of appeal brief). Appellant then argues that Tomonto does not teach the compositions of these metals, their thermal annealing histories, work hardening histories, etc. in order to determine which is more elastic. However, the instant specification only broadly teaches metal such as Nitinol as the second material and stainless steel as the first and does not give chemical characteristics of each to determine their elasticity (see paragraphs [0048] and [0055] of the instant specification). Therefore, since the specification does not differentiate between different Nitinols and stainless steels, it is the Examiner's position that the Nitinol and stainless steel of Tomonto overlap the instantly claimed metals.

Furthermore, Appellant argues that there are over 150 grades of stainless steel each with a variety of elasticity. However, Appellant has not provided one example of a stainless steel variety that is more elastic than a variety of Nitinol commonly used in the stent art. Therefore, it is the Examiner's position that the metals disclosed by Tomonto overlap the claimed metals.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/AMY LANG/
Examiner, Art Unit 3731
9/16/2010

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3731
September 27, 2010

/David Okonsky/
Primary Examiner, Art Unit 3700

Conferees:
Gary Jackson
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